

FEDERAL REGISTER INDEX

January–April 2014

Food and Drug Administration

RULES

Administrative Detention; Corrections – 9412 (Feb 19)

Draft Guidance for Industry and Staff:

- Establishment, Maintenance, and Availability of Records – 18799 (Apr 4)
- Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula – 7933 (Feb 10)
- Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula; Correction – 9412 (Feb 19)
- Medicated Feeds; Manufacturing Practice – 3738 (Jan 23)
- Pharmacy Compounding Advisory Committee; Charter Changes – 2093 (Jan 13)

Food Additives; Animals Feeds:

- Benzoic Acid – 14175 (Mar 13)

Food Additives; Human Consumption:

- Spirulina Extract; Color Additives; Exempt from Certification – 20095 (Apr 11)
- Vitamin D2 in Bakers Yeast – 13540 (Mar 11)

Food Labeling:

- Irradiation in the Production, Processing, and Handling of Food – 10353 (Feb 25); 20771 (Apr 14)
- Nutrient Content Claims; Alpha-Linolenic Acid, Eicosapentaenoic Acid, and Docosahexaenoic Acid Omega-3 Fatty Acids – 23262 (Apr 28)

Maximum Civil Money Penalty Amounts; Civil Money Penalty Complaints – 6088 (Feb 3)

Medical Devices:

- Classification of the Neuropsychiatric Interpretive Electroencephalograph Assessment Aid – 9083 (Feb 18)
- Electronic Submission Requirements – 8832 (Feb 14)
- General and Plastic Surgery Devices; Classification of the Absorbable Lung Biopsy Plug – 13218 (Mar 10)
- Immunology and Microbiology Devices; Classification of John Cunningham Virus Serological Reagents – 3739 (Jan 23)
- Ophthalmic Devices; Classification of the Eyelid Weight – 22012 (Apr 21)
- Pediatric Uses of Devices; Requirement for Submission of Information – 1735 (Jan 10)
- Reclassification of Stair-Climbing Wheelchairs – 20779 (Apr 14)
- Reports of Corrections and Removals; Technical Amendment – 9413 (Feb 19)

Meetings:

- Bone, Reproductive and Urologic Drugs Advisory Committee; Charter Changes – 20094 (Apr 11)

New Animal Drugs:

- Amprolium; Bambermycins; Ceftiofur; Deslorelin; Florfenicol; Florfenicol and Flunixin; Paclitaxel; Phenylbutazone; Pimobendan; Salinomycin; Tilmicosin; Tiludronate – 18156 (Apr 1)
- Argent Laboratories; Formalin; Tricaine Methanesulfonate; Withdrawal – 2785, 2786 (Jan 16)
- Bambermycins, Hygromycin B, Lincomycin, Pyrantel, Tylosin, Tylosin and Sulfamethazine, Virginiamycin – 19814, 19816 (Apr 10)
- Bambermycins; Clopidol; Ivermectin; et al.; Change of Sponsor; Change of Sponsor Address – 10963 (Feb 27)
- Ceftiofur Sodium; Gentamicin; Xylazine – 21126 (Apr 15)
- Changes of Sponsors – 10965 (Feb 27); 13542 (Mar 11)
- Chlortetracycline; Sulfathiazole; Penicillin; Withdrawal – 15540, 15541 (Mar 20)
- Confidentiality of Data and Information in a New Animal Drug Application File – 14609 (Mar 17)
- Implantation or Injectable Dosage Form; Change of Sponsor – 16180 (Mar 25)
- Zoetis Inc., et al.; Medicated Feeds Containing an Arsenical Drug; Correction – 18990 (Apr 7)

- Zoetis Inc., et al.; Withdrawal of Approval; Combination Drug Medicated Feeds Containing an Arsenical Drug – 10974, 10976 (Feb 27)
- Zoetis, Inc., al.; Combination Drug Medicated Feeds Containing an Arsenical Drug; Correction – 17859 (Mar 31)

Premarket Approvals:

- Transilluminator for Breast Evaluation and Sorbent Hemoperfusion System Devices for Treatment of Hepatic Coma and Metabolic Disturbances; etc. – 3088 (Jan 17)

PROPOSED RULES

Draft Guidance for Industry and Staff:

- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals – 6111 (Feb 3)
- Demonstration of the Quality Factor Requirements for Eligible Infant Formulas; Availability – 7609 (Feb 10)
- Draft Qualitative Risk Assessments; Outside the Farm Definition – 16251 (Mar 25)
- Exempt Infant Formula Production; Current Good Manufacturing Practices, Quality Control Procedures, Conduct of Audits, and Records and Reports; Availability – 7610 (Feb 10)
- Focused Mitigation Strategies to Protect Food Against Intentional Adulteration – 16251 (Mar 25)
- Focused Mitigation Strategies to Protect Food Against Intentional Adulteration; Meetings – 5353 (Jan 31)
- Imported Food Questions and Answers – 17947 (Mar 31)
- Qualitative Risk Assessment of Risk of Activity/Animal Food Combinations; Conducted in a Facility Co-Located on a Farm – 6116 (Feb 3)
- Records Access Authority under the Federal Food, Drug, and Cosmetic Act – 18866 (Apr 4)
- Sanitary Transportation of Human and Animal Food – 7005 (Feb 5)
- What You Need To Know About Establishment, Maintenance, and Availability of Records; Small Entity Compliance Guide – 18867 (Apr 4)

Environmental Impact Statements; Availability, etc.:

- Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption – 13593 (Mar 11)

Food Additive Petitions; Animal Use:

- Novus International, Inc. – 22910 (Apr 25)

Food Additives; Animal Use:

- DSM Nutritional Products – 16252 (Mar 25); 16698 (Mar 26)
- Excentials B.V. – 22602 (Apr 23)
- Kemin Industries, Inc. – 13263 (Mar 10)
- Lohmann Animal Health GMBH – 7611 (Feb 10)

Food Additives; Petitions:

- Eastman Chemical Co. – 19301 (Apr 8)

Food Labeling:

- Revision of the Nutrition and Supplement Facts Labels – 11879 (Mar 3)
- Serving Sizes of Foods that Can Reasonably Be Consumed at One-Eating Occasion, etc. – 11989 (Mar 3)
- Serving Sizes; Reference Amount and Serving Size Declaration for Hard Candies, Breath Mints – 11738 (Mar 3)

Food Safety Modernization Act:

- Food Registry Provisions of Federal Food, Drug, and Cosmetic Act; Amendments – 16698 (Mar 26)

Generic Drug User Fee Amendments:

- Regulatory Science Initiatives; Public Hearing – 10740 (Feb 26)

Maximum Civil Money Penalty Amounts; Civil Money Penalty Complaints – 6112 (Feb 3)

Medical Devices:

- Medical Device Classification Procedures – 16252 (Mar 25)

National Environmental Policy Act:

- Tobacco Products; Categorical Exclusions – 3742 (Jan 23)

New Animal Drugs:

- Confidentiality of Data and Information in a New Animal Drug Application File – 14630 (Mar 17)

Physical Medicine Devices:

Food and Drug Administration

Action Plan for Collection, Analysis, and Availability of Demographic Subgroup Data; Regulated Medical Products; Public Hearings – 12134 (Mar 4)

Cardiovascular Devices; Nonroller-Type Cardiopulmonary Bypass Blood Pumps for Cardiopulmonary and Circulatory Bypass; etc.; Reclassification – 765 (Jan 7)

Premarket Approval for Shortwave Diathermy for All Other Uses; Withdrawal – 9670 (Feb 20)

Shortwave Diathermy for All Other Uses; Reclassification – 9671 (Feb 20)

Sanitary Transportation of Human and Animal Food – 8907 (Feb 14)

Tobacco Products:

- Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products – 23141 (Apr 25)

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

- Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded – 16007 (Mar 24)
- Adverse Event Program for Medical Devices (Medical Product Safety Network) – 20887 (Apr 14)
- Adverse Experience Reporting for Licensed Biological Products; and General Records – 19097 (Apr 7)
- Animal Drug User Fee Act Cover Sheet – 6199 (Feb 3); 22689 (Apr 23)
- Animal Drug User Fee Act Waivers and Reductions – 10532 (Feb 25)
- Animal Feed Network; State, Federal Cooperation to Prevent Spread of Pet Food and Animal Feed Related Diseases – 10529 (Feb 25)
- Animal Feed Regulatory Program Standards – 9223 (Feb 18)
- Animal Generic Drug User Fee Act Cover Sheet – 9224 (Feb 18); 22687 (Apr 23)
- Application for Food and Drug Administration Approval to Market a New Drug – 16003 (Mar 24)
- Application for Participation in the Medical Device Fellowship Program – 3819 (Jan 23); 19619 (Apr 9)
- Chemistry, Manufacturing, and Controls Postapproval Manufacturing Changes to be Documented in Annual Reports – 9215 (Feb 18)
- Color Additive Certification Requests and Recordkeeping – 7199 (Feb 6); 22688 (Apr 23)
- Cosmetic Labeling Regulations – 21766 (Apr 17)
- Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements – 10530 (Feb 25)
- Current Good Manufacturing Practice Regulations for Medicated Feeds – 19091 (Apr 7)
- Current Good Manufacturing Practice Regulations for Type A Medicated Articles – 19093 (Apr 7)
- Current Good Manufacturing Practice; Quality System Regulation – 9908 (Feb 21)
- Customer/Partner Service Surveys – 21765 (Apr 17)
- Data to Support Drug Product Communications as Used by the Food and Drug Administration – 19096 (Apr 7)
- Designation of New Animal Drugs for Minor Use or Minor Species; Final Rule – 14713 (Mar 17)
- Electronic Records; Electronic Signatures – 17551 (Mar 28)
- Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products – 16800 (Mar 26)
- Establishing and Maintaining Lists of United States Milk Product Manufacturers/Processors with Interest in Exporting – 9221 (Feb 18)
- Evaluation of the General Market Youth Tobacco Prevention Campaign – 11112 (Feb 27)
- Exception from General Requirements for Informed Consent – 19915 (Apr 10)
- Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile – 9219 (Feb 18)
- Eye Tracking Experimental Studies to Explore Consumer Use of Food Labeling Information, etc. – 14713 (Mar 17)
- Focus Groups as Used by the Food and Drug Administration – 9222 (Feb 18)
- Food and Drug Administration Generic Rapid Response Surveys – 19618 (Apr 9)
- Food and Drug Administration Safety Communication Readership Survey – 7677 (Feb 10)
- General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions – 15594 (Mar 20)

General Licensing Provisions: Biologics License Application, Changes, etc. – 3821 (Jan 23)

Guidance for Industry and Food and Drug Administration Staff on Improving Communication of Important Safety Information – 3209 (Jan 17)

Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to the Federal Food, Drug, and Cosmetic Act – 13656 (Mar 11)

Guidance for Industry on Pharmacogenomic Data Submissions – 7198 (Feb 6)

Guidance for Industry on Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products, etc. – 19099 (Apr 7)

Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables – 4350 (Jan 27)

Hazard Analysis and Critical Control Point Procedures for the Safe and Sanitary Processing and Importing of Juice; Comment Request – 4347 (Jan 27)

Human Cells, Tissues, and Cellular and Tissue-Based Products, etc. – 3822 (Jan 23)

Human Tissue Intended for Transplantation – 9467 (Feb 19)

Importer's Entry Notice – 14255 (Mar 13)

Index of Legally Marketed Unapproved New Animal Drugs for Minor Species – 19094 (Apr 7)

Information from United States Firms and Processors that Export to the European Community – 11446 (Feb 28)

Institutional Review Boards – 12202 (Mar 4)

Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products, etc. – 3826 (Jan 23)

Medical Devices; Device Tracking – 22991 (Apr 25)

Medical Devices; Third Party Review under the Food and Drug Administration Modernization Act – 9215 (Feb 18)

Orphan Drugs Products; Common European Medicines Agency/FDA Application Form for Orphan Medicinal Product Designation – 21471 (Apr 16)

Over-the-Counter Human Drugs; Labeling Requirements – 9217 (Feb 18)

Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions – 7678 (Feb 10)

Potential Tobacco Product Violations Reporting Form – 9216 (Feb 18)

Premarket Approval of Medical Devices – 3210 (Jan 17)

Premarket Notification for a New Dietary Ingredient – 15129 (Mar 18)

Premarket Notification Submission 510(k) – 3210 (Jan 17)

Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition – 15130 (Mar 18)

Prescription Drug Advertisements – 11112 (Feb 27)

Procedures for the Safe Processing and Importing of Fish and Fishery Products – 14713 (Mar 17)

Protection of Human Subjects; Informed Consent; Institutional Review Boards – 3826 (Jan 23)

Qualitative Feedback on Agency Service Delivery – 23980 (Apr 29)

Radioactive Drug Research Committees – 4348 (Jan 27); 24442 (Apr 30)

Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices, etc. – 3820 (Jan 23); 16799 (Mar 26)

Recordkeeping and Records Access Requirements for Food Facilities – 21767 (Apr 17)

Reporting and Recordkeeping for Electronic Products; General Requirements – 3210 (Jan 17)

Reports of Corrections and Removals of Medical Devices and Radiation Emitting Products – 17549 (Mar 28)

Requests for Feedback on Medical Device Submissions – 3821 (Jan 23)

Risk and Benefit Perception Scale Development – 22143 (Apr 21)

Risks in Direct-to-Consumer Prescription Drug Television Advertisements – 9217 (Feb 18)

Standards for Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format – 9745 (Feb 20)

Submission of Petitions; Food Additive, Color Additive, and Generally Recognized as Safe Affirmation, etc. – 21469 (Apr 16)

Testing Communications on Medical Devices and Radiation-Emitting Products – 18558 (Apr 2)

Tobacco Health Document Submission – 3820 (Jan 23)

Total Product Life Cycle; Infusion Pump; Premarket Notification Submissions; Draft Guidance for Industry and Staff – 19616 (Apr 9)

Use of Serological Tests to Reduce the Risk of Transmission of Trypanosoma cruzi Infection in Whole Blood and Blood Components for Transfusion – 12506 (Mar 5)	Fees for Human Drug Compounding Outsourcing Facilities under the Food, Drug, and Cosmetic Act – 18297 (Apr 1)
User Fee Waivers, Reductions, and Refunds for Drug and Biological Products – 12201 (Mar 4)	Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal Drugs and Biologics – 2449 (Jan 14)
Voluntary Cosmetic Registration Program – 7196 (Feb 6); 23981 (Apr 29)	Guidance for Industry on Pharmacogenomic Data Submissions – 23359 (Apr 28)
Voluntary National Retail Food Regulatory Program Standards – 6200 (Feb 3)	Guidance for Industry on Special Protocol Assessment – 7676 (Feb 10)
Determinations that Products Were Not Withdrawn from Sale for Reasons of Safety or Effectiveness:	Humanitarian Device Exemption, Questions and Answers – 15130 (Mar 18)
Cefmetazole Sodium Injection, Equivalent to 1 Gram Base/Vial and Equivalent to 2 Gram Base/Vial, etc. – 13307 (Mar 10)	Immunogenicity-Related Considerations for Approval of Low Molecular Weight Heparin for New Drug Applications – 19621 (Apr 9)
Darunavir Tablets, 400 Milligrams – 18558 (Apr 2)	Ingredients Declared as Evaporated Cane Juice Ingredients – 12507 (Mar 5)
Gallium Nitrate Injectable and Five Other Drug Products – 9225 (Feb 18)	International Conference on Harmonisation; E2B(R3) Electronic Transmission of Individual Case Safety Reports, etc. – 9908 (Feb 21)
Metaxalone Tablets, 400 Milligrams – 19102 (Apr 7)	Interpreting Sameness of Monoclonal Antibody Products under Orphan Drug Regulations – 22693 (Apr 23)
Nimodipine Capsules, 30 Milligrams – 18559 (Apr 2)	Investigational New Drug Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood, etc. – 12509 (Mar 5)
Valproic Acid Delayed-Release Capsules, 125 Milligrams, 250 Milligrams, and 500 Milligrams – 9225 (Feb 18)	Labeling for Human Prescription Drug and Biological Products Approved under the Accelerated Approval Regulatory Pathway – 16344 (Mar 25)
Zovirex Injection, Equivalent to 250 Milligrams Base/Vial, et al. – 20214 (Apr 11)	Live Case Presentations During Investigational Device Exemption Clinical Trials – 21776 (Apr 17)
Draft Guidance for Industry and Staff:	Meaning of "Spouse" and "Family" in FDA Regulations after United States v. Windsor – 18693 (Apr 3)
Advisory Committee Members' Financial Interest Information and Waivers – 18032 (Mar 31)	Medical Devices Containing Materials Derived From Animal Sources – 3826 (Jan 23)
Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products – 14517 (Mar 14)	Meetings with the Office of Orphan Products Development – 19623 (Apr 9)
Analgesic Indications; Developing Drug and Biological Products – 7203 (Feb 6)	New Chemical Entity Exclusivity Determinations for Fixed-Combination Drug Products – 10167 (Feb 24)
Analytical Procedures and Methods Validation for Drugs and Biologics – 9467 (Feb 19)	Pediatric Studies; Sodium Nitroprusside; Summary Report, Labeling Changes – 4167 (Jan 24)
Attachment to Guidance on Antiviral Product Development; Conducting and Submitting Virology Studies to the Agency; etc. – 11448 (Feb 28)	Premarket Approval Applications; Annual Reports – 7679 (Feb 10)
Balancing Premarket and Postmarket Data Collection for Devices Subject to Premarket Approval – 22690 (Apr 23)	Premarket Notification Submissions for Bipolar Electrosurgical Vessel Sealers for General Surgery – 16009 (Mar 24)
Bioavailability and Bioequivalence Studies Submitted in New Drug Applications or Investigational New Drug Applications – 15131 (Mar 18)	Premarket Notification Submissions for Electrosurgical Devices for General Surgery – 16008 (Mar 24)
Biologics License Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood, etc. – 12508 (Mar 5)	Product-Specific Bioequivalence Recommendations – 18561 (Apr 2)
Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use – 830 (Jan 7); 19622 (Apr 9)	Proper Labeling of Honey and Honey Products – 19620 (Apr 9)
Center for Biologics Evaluation and Research Move to White Oak Campus – 12506 (Mar 5)	Providing Regulatory Submissions in Electronic Format--Standardized Study Data; Revision – 7201 (Feb 6)
Center for Devices and Radiological Health – 16801 (Mar 26)	Providing Regulatory Submissions in Electronic Format--Submissions under the Federal Food, Drug, and Cosmetic Act – 7200 (Feb 6)
Chemistry, Manufacturing, and Controls Postapproval Manufacturing Changes to be Documented in Annual Reports – 12511 (Mar 5)	Providing Regulatory Submissions in Electronic Format; Receipt Date; Correction – 11449 (Feb 28)
Chronic Fatigue Syndrome/Myalgic Encephalomyelitis; Development of Drug Products for Treatment; Availability – 13658 (Mar 11)	Qualification of Exacerbations of Chronic Pulmonary Disease Tool for Measurement of Symptoms of Acute Bacterial Exacerbation of Chronic Bronchitis, etc. – 1873 (Jan 10)
Community-Acquired Bacterial Pneumoni; Developing Drugs for Treatment – 1874 (Jan 10)	Qualification Process for Drug Development Tools – 831 (Jan 7)
Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements – 2450 (Jan 14)	Questions and Answers About Electronic Medical Device Reporting – 8977 (Feb 14)
Custom Device Exemption – 2446 (Jan 14)	Regulatory Submissions in Electronic Format – 7463 (Feb 7)
Dear Health Care Provider Letters; Improving Communication of Important Safety Information – 3827 (Jan 23)	Report on Performance of Drug and Biologics Firms in Conducting Postmarketing Requirements and Commitments – 9230 (Feb 18)
Designation of High-Risk Foods for Tracing – 6596 (Feb 4)	Reporting of Computational Modeling Studies in Medical Device Submissions – 3211 (Jan 17)
Designation of High-Risk Foods for Tracing and for Scientific Data and Information – 16800 (Mar 26)	Reports to Congress; Premarket Notification Requirements for Modifications to Legally Marketed Devices – 12695 (Mar 6)
Determining whether Human Research Studies can be Conducted without an Investigational New Drug Application; Reopening of the Comment Period – 7204 (Feb 6)	Requests for Feedback on Medical Device Submissions; Pre-Submission Program and Meetings with FDA Staff – 9226 (Feb 18)
Distinguishing Liquid Dietary Supplements from Beverages – 2451 (Jan 14)	Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use – 829 (Jan 7); 19622 (Apr 9)
Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices – 11793 (Mar 3)	Study Data Technical Conformance Guide and Data Standards Catalog – 7204 (Feb 6)
Endotoxin Testing Recommendations for Single-Use Intraocular Ophthalmic Devices – 21777 (Apr 17)	Submitting Food Canning Establishment Registration Form, etc., in Electronic or Paper Format – 2448 (Jan 14)
Enforcement Policy for Certain Tobacco Products that the Food and Drug Administration Finds Not Substantially Equivalent – 10534 (Feb 25)	Training Program for Regulatory Project Managers; Information Available to Industry – 9912 (Feb 21)
Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat Clostridium difficile Infection Not Responsive to Standard Therapies – 10814 (Feb 26)	Transparency Initiative – 22693 (Apr 23)
Expedited Access for Premarket Approval Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Disease or Conditions – 22691 (Apr 23)	Types of Communication During the Review of Medical Device Submissions – 18918 (Apr 4)
	Drugs for Human Use:
	Certain Prescription Drugs Offered for Various Indications – 1875 (Jan 10)

Food and Drug Administration

- Unapproved and Misbranded Oral and Injectable Drugs Labeled for Prescription Use Containing Codeine Sulfate, Codeine Phosphate, or Dihydrocodeine Bitartrate; Enforcement Action Dates – 1879 (Jan 10)
- Use of Innovative Packaging, Storage, and/or Disposal Systems to Address the Misuse and Abuse of Opioid Analgesics – 19619 (Apr 9)
- Environmental Impact Statements; Availability, etc.:
Risk-Based Regulatory Framework and Strategy for Health Information Technology Report; Report and Web Site Location – 19100 (Apr 7)
- Funding Availability:
Illinois Institute of Technology's National Center for Food Safety and Technology; Cooperative Agreement – 23360 (Apr 28)
- List of Recognized Standards:
Recognition List Number 033; Modifications – 2453 (Jan 14)
Recognition List Number 034; Modifications – 4913 (Jan 30)
- Medical Devices:
Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Novel Influenza A (H7N9) Virus; Availability – 21768 (Apr 17)
Safety and Effectiveness Summaries for Premarket Approval Applications – 14053, 14053 (Mar 12)
- Meetings:
Advancing Regulatory Science for High Throughput Sequencing Devices for Microbial Identification, etc. – 13062 (Mar 7)
Advancing the Development of Pediatric Therapeutics; Pediatric Bone Health – 7205 (Feb 6); 21473 (Apr 16)
Advisory Committees; Filing of Closed Meeting Reports – 10814 (Feb 26)
American Glaucoma Society/Supporting Innovation for Safe and Effective Minimally Invasive Glaucoma Surgery – 6203 (Feb 3)
Anesthesiology and Respiratory Therapy Devices Panel of the Medical Devices Advisory Committee – 1382 (Jan 8)
Anesthetic and Analgesic Drug Products Advisory Committee – 16010 (Mar 24)
Anti-Infective Drugs Advisory Committee – 8462 (Feb 12)
Application of Physiologically-Based Pharmacokinetic Modeling to Support Dose Selection – 8192 (Feb 11)
Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee – 1384 (Jan 8)
Biofilms, Medical Devices, and Anti-Biofilm Technology; Public Workshop – 4166 (Jan 24)
Blood Products Advisory Committee – 9909 (Feb 21)
Cardiovascular and Renal Drugs Advisory Committee – 1384 (Jan 8); 1646 (Jan 9); 13064 (Mar 7)
Characterizing and Communicating Uncertainty in the Assessment of Benefits and Risks in Drug Regulatory Decision-Making – 21475 (Apr 16)
Characterizing and Communicating Uncertainty in the Assessment of Benefits and Risks in Drug Regulatory Decision-Making; Public Workshop – 1877 (Jan 10)
Circulatory System Devices Panel, Medical Devices Advisory Committee – 20888 (Apr 14)
Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practice; Public Workshop – 3829 (Jan 23)
Endocrinologic and Metabolic Drugs Advisory Committee – 9911 (Feb 21)
FDA and Global Engagement: Progress on the Pathway to Global Product Safety – 18033 (Mar 31)
FDA/Xavier University PharmaLink Conference; Leadership in a Global Supply Chain – 9229 (Feb 18)
Fibromyalgia, Patient-Focused Drug Development; Rescheduling – 9468 (Feb 19)
Food and Drug Administration/Xavier University Global Medical Device Conference – 10815 (Feb 26)
Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee – 8722 (Feb 13); 22147 (Apr 21)
Medical Countermeasures Initiative Regulatory Science Symposium – 9230 (Feb 18)
Medical Devices; The Case for Quality – 9469 (Feb 19)
Methods for Thrombogenicity Testing; Public Workshop – 14054 (Mar 12)
Microbiology Devices Panel of the Medical Devices Advisory Committee – 3388 (Jan 21)
Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee – 6908 (Feb 5)
Neurological Devices Panel of the Medical Devices Advisory Committee – 17155 (Mar 27)
- Next-Generation Sequencing Technology, Data Formats Standardization and Promotion of Interoperability Protocols – 22147 (Apr 21)
- Nonprescription Drugs Advisory Committee – 1381 (Jan 8); 20215 (Apr 11)
- Nonprescription Drugs and Pulmonary-Allergy Drugs Advisory Committees – 1383 (Jan 8)
- Oncologic Drugs Advisory Committee – 22146 (Apr 21)
- Ophthalmic Devices Panel of the Medical Devices Advisory Committee – 11796 (Mar 3); 20889 (Apr 14)
- Over-The-Counter Drug Monograph System; Past, Present, and Future – 10168 (Feb 24)
- Patient-Focused Drug Development for Neurologic Manifestations of Inborn Errors of Metabolism – 22994 (Apr 25)
- Pediatric Advisory Committee – 2452 (Jan 14); 18034 (Mar 31)
- Pediatric Clinical Investigator Training Workshop – 23982 (Apr 29)
- Postmarketing Requirements for the Class-Wide Extended-Release/Long-Acting Opioid Analgesics – 22499 (Apr 22)
- Preparation for International Cooperation on Cosmetics Regulation – 22993 (Apr 25)
- Proposal to Revoke Allergy Laboratories, Inc. License – 24443 (Apr 30)
- Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee – 22995 (Apr 25)
- Pulmonary Arterial Hypertension; Patient-Focused Drug Development – 7464 (Feb 7)
- Risk Communications Advisory Committee – 398 (Jan 3); 3830 (Jan 23); 11797 (Mar 3)
- Risk-Based Framework for Food and Drug Administration Safety and Innovation Act Health Information Technology; Public Workshop – 21473 (Apr 16)
- Science Board – 3831 (Jan 23)
- Science Board to the Food and Drug Administration – 1645 (Jan 9)
- Serious Drug-Induced Liver Injury; Who Gets It? Who Doesn't? Why? – 7680 (Feb 10)
- Society of Clinical Research Associates; Public Workshop – 9471 (Feb 19)
- Standards for Interoperable Exchange of Information for Tracing of Human, Finished, Prescription Drugs, in Paper or Electronic Format; Workshop – 18562 (Apr 2)
- Study Approaches and Methods to Evaluate Safety of Drugs and Biological Products During Pregnancy in Post-Approval Setting – 9469 (Feb 19)
- Synergizing Efforts in Standards Development for Cellular Therapies and Regenerative Medicine Products; Public Workshop – 8462 (Feb 12)
- Tobacco Products Scientific Advisory Committee – 9910 (Feb 21)
- Vaccines and Related Biological Products Advisory Committee – 5439 (Jan 31); 8463 (Feb 12)
- Voting and/or Nonvoting Consumer Representatives on Public Advisory Committees or Panels; Nominations – 16010 (Mar 24)
- National Environmental Policy Act:
Canned Ackee, Frozen Ackee, and Other Ackee Products - Hypoglycin A Toxin – 21250 (Apr 15)
- New Drug Applications:
AbbVie Inc., et al.; Acetaminophen; Withdrawals – 17156 (Mar 27)
Actavis Totowa, LLC, et al.; Acetaminophen; Withdrawals – 17163 (Mar 27)
Eli Lilly and Co., et al.; Withdrawals – 22501 (Apr 22)
Improving the Quality of Abbreviated Submissions – 3828 (Jan 23)
MK Laboratories, Inc., et al.; Propoxyphene Products – 13310 (Mar 10)
Phenylpropanolamine; Withdrawal of Approval – 9744 (Feb 20)
Xanodyne Pharmaceuticals, Inc., et al.; Propoxyphene Products – 13308 (Mar 10)
- Premarket Approvals:
Watson Laboratories, Inc.; Bupropion Hydrochloride Extended-Release Tablets, 300 Milligrams; Withdrawal – 19626 (Apr 9)
- Priority Review Vouchers:
Rare Pediatric Disease Product – 14055 (Mar 12)
- Regulatory Review Period for Patent Extensions:
BRILINTA – 24444 (Apr 30)
DALIRESP – 3831 (Jan 23)
EYLEA – 18566 (Apr 2)
FIRAZYR – 18565 (Apr 2)
GADAVIST – 3832 (Jan 23)
MELAFIND SYSTEM – 19101 (Apr 7)
NOVOTFF-100A SYSTEM – 18567 (Apr 2)
NULOJIX – 18036 (Mar 31)
ONSIOR – 18563 (Apr 2)
POTIGA – 18564 (Apr 2)
PREVNAR-13 – 18035 (Mar 31)

Requests for Nominations:

Nonvoting Industry Representatives on Public Advisory Panels – 3390
(Jan 21)
Nonvoting Industry Representatives on the Device Good Manufacturing
Practice Advisory Committee – 3389 (Jan 21)
Pharmacy Compounding Advisory Committee – 2178 (Jan 13)

Pharmacy Compounding Advisory Committee, Nonvoting Industry
Representatives – 2177 (Jan 13)
Pharmacy Compounding Advisory Committee, Voting Members – 2179
(Jan 13)
Science Board – 6204 (Feb 3)
Selections Process for Non-Voting Industry Representatives – 22148 (Apr 21)